

REMARKS

Status

Claims 1-7, 10-17, 19-21, and 44-47 are pending. Claims 1-7, 10-17, 19, and 20 stand rejected under 35 USC §103. Claims 44-45 are objected to as being dependent on a rejected base claim. Claims 46-47 are allowed. Applicant traverses the rejections of the claims under 35 USC §103 based on the arguments provided herein and requests reconsideration and allowance.

Claim Rejections

Claims 1-7, 10-11, 14-15, and 19 were rejected under 35 USC §103(a) as being unpatentable over US Patent Pub. No. 2004/0009096 (Wellman) in view of US Patent No. 3,799,873 (Brown). Claims 1-7, 10-11, 14-15, and 20 were rejected under 35 USC §103(a) as being unpatentable over Wellman in view of US Patent No. 3,939,069 (Granger). Claims 1-7, 10-14, 16, and 19 were rejected under 35 USC §103(a) as being unpatentable over US Patent No. 5,948,684 (Weigl) in view of US Patent Pub. 2003/0034306 (Schulte) and Brown. Claims 1-7, 10-14, 16, and 20 were rejected under 35 USC §103(a) as being unpatentable over Weigl in view of Schulte and Granger. Claim 15 was rejected under 35 USC §103(a) as being unpatentable over Weigl in view of Schulte and Brown as applied to claim 14, and further in view of US 2002/0052571 (Fazio). Claim 17 was rejected under 35 USC §103(a) as being unpatentable over Weigl in view of Schulte and Brown as applied to claim 1, and further in view of US Pat. No. 5,932,100 (Yager).

A *prima facie* case of obviousness under 35 USC §103 requires (1) a motivation to combine references, (2) a reasonable expectation of success, and (3) a teaching or suggestion of claimed features. *MPEP* §2142. As explained below, none of the Office Action, the cited references, and the prior art provides any motivation to combine the cited references in the manner indicated in the Office Action. A *prima facie* case of obviousness of claims 1-7, 10-17, 19, and 20 thus fails.

All of the rejections of claims 1-7, 10-17, 19, and 20 ultimately rely on the combinations of Wellman or Weigl with either Brown or Granger. These combinations do not support a *prima facie* case of obviousness for the reasons enumerated below.

1. The proposed combination of Wellman or Weigl with Brown would generate a therapeutic device that removes essential components from the blood. Such a device would be unsatisfactory for its intended therapeutic purpose. Based on *MPEP* 2143.07 V, the proposed combination of Wellman or Weigl with Brown therefore cannot support a *prima facie* case of obviousness.

As explained by Applicant, membraneless separators are poor at discriminating between blood components to be retained in treatment, such as macromolecules and blood proteins, and those that are not. *Specification (as filed)*: p. 16, l. 5 through p. 17, l. 35. As a result, these larger blood components cross into the dialysate. The filter 60 in Brown removes all components from spent dialysate except electrolytes and pure water. Brown, col. 1, ll. 20-25, and col. 4, ll. 4-9. By removing all components except electrolytes and water, the Brown filter, combined with the membraneless contactor of Wellman or Weigl, would deplete macromolecular blood components such as fibrinogen, globulins, and albumin, thereby rendering the proposed combination unsatisfactory for the intended use. Thus, Brown fails to teach or suggest the use of the recycle loop and filter in devices such as those of Wellman or Weigl. *MPEP* §2143.07 I. In summary, none of Wellman, Weigl, and Brown provides any motivation to modify Wellman or Weigl with Brown in the manner indicated in the Office Action. See also *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (stating, “in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.”). Accordingly, the §103 rejections of claims 1-7, 10-17, and 19 which rely on the combination of Wellman or Weigl with Brown should be withdrawn, and claims 1-7, 10-17, and 19 should be allowed.

2. The proposed combination of Wellman or Weigl with Granger would also generate a device unsatisfactory for its intended purpose. Based on *MPEP* 2143.07 V, the proposed combination of Wellman or Weigl with Granger cannot support a *prima facie* case of obviousness.

First, the purpose of providing the closed circuit 5 of Granger is to achieve a fixed-volume vessel on the dialysate-side of the dialyzer. Granger, col. 1, ll. 45-58. This causes the volume of dialysate drawn from the circuit 5 by the pump 8 to correspond precisely to the

volume of fluid removed from the blood. However, as Granger indicates, a pressure difference arises between blood and dialysate (Granger, col. 2, ll. 10-15.) Membraneless fluid contactors do not have a membrane corresponding to that of the dialyzer 1 and therefore are not intended to tolerate pressure differences across the boundary between co-flowing streams. This is because such pressure differences would force dialysate into the blood or draw blood directly into the dialysate. Thus, the closed circuit's function cannot be applied in combination with a membraneless device such as shown by Wellman or Weigl. Second, since, as explained by Applicant, plasma components are transferred across a membraneless contactor, the activated charcoal adsorber 7 shown by Granger would fail in its ability to remove urea due to the accumulation of heavy plasma constituents on the adsorber, rendering the device unsatisfactory for the intended purpose. In addition, even if the amount of adsorbent were increased to avoid this problem, essential blood components would then be removed by the adsorber from the bloodstream, which, as explained above, would also render the result unsatisfactory for the intended purpose.

The Office Action highlighted Weigl's statement that "larger particles show no significant diffusion within the time the streams are in contact with each other in flow channel (100)." However, this general statement has little relevance in the context of renal therapy. In the quoted passage, Weigl discussed the diffusion of small ions. In renal therapy, urea and middle molecules, with their higher molecular weights, must diffuse into the dialysate. In addition, the devices and methods discussed by Weigl relate to sample analysis, and as such, Weigl describes co-flowing sample and indicator streams, which are not repeatedly cycled through the membraneless contactor. In dialysis, any given volume of blood must make many passes through the dialyzer because, urea, for example, which is stored throughout the total body fluid compartment, must diffuse into the blood after the blood is depleted of urea by the dialyzer. Thus each cycle of blood through the dialyzer can only carry a limited fraction of the total waste load into the dialyzer. As a result, larger molecules, which reside only in the blood, are repeatedly passed through the dialyzer causing their loss to the dialysate stream to be higher than smaller constituents, even though the smaller constituent diffusion rates are higher. *Specification (as filed)*: p. 16, ll. 25-31. Moreover, a blood treatment device must maintain fluid balance in the

body of the person being treated. Relatively small quantities of substances diffusing across the fluid boundary in the membraneless device cannot simply be ignored because the receiving fluid volumes must be appropriately apportioned between the exiting dialysate stream and the patient. This is so lest excess water be injected into the patient or essential blood components be removed. Thus even small quantities of desirable blood components must be permitted to enter the dialysate stream where their cumulative loss would become substantial.

For the foregoing reasons, the §103 rejections of claims 1-7, 10-11, 14-15, 16, and 20, which rely on the combination of Wellman or Weigl with Granger, should be withdrawn, and claims 1-7, 10-11, 14-15, 16, and 20 should be allowed.

3. One of ordinary skill in the art would not have any motivation to modify Weigl in the manner suggested by either Brown or Granger because Weigl, Brown, and Granger are directed to unrelated endeavors. The Office Action proposes that one of ordinary skill in the art would have been motivated to modify Weigl based on Brown or Granger so that the Weigl device could then remove “toxic solutes,” as suggested by Brown. However, Weigl relates to the analysis of small fluid samples, and not to treatments for end-stage renal disease as do Brown and Granger. Moreover, the reference in Brown to “toxic solutes” relates to the blood cleansing function of the Brown apparatus, while Weigl says nothing about removing blood toxins. Given the unrelated teachings of Weigl, Brown, and Granger, it is not at all clear where one of ordinary skill in the art would have found a motivation to make the proposed modification of Weigl. Indeed, such a motivation could not have been found in either Brown or Granger. Brown states that the purpose of recycling dialysate is to make portable a treatment device that attaches to a living patient. Brown col. 2, ll. 27-31. Brown thus fails to teach to combine the recycling of fluid with the sample analyzers of Weigl. Granger states that the motivation for using a closed loop is that it provides a way to control the quantity of ultrafiltrate, which is a fluid-balance function associated with renal replacement therapy treatment. Granger thus does not teach to combine the closed loop with the sample analyzers of Weigl. Accordingly, the §103 rejections of claims 1-7, 10-17, 19, and 20, which rely on the combination of Weigl with Brown or Granger should be withdrawn, and claims 1-7, 10-17, 19, and 20 should be allowed.

Summary

As previously indicated, all of the claim rejections, including those of the dependent claims, ultimately rely on combinations of Wellman or Weigl with either Brown or Granger. As such, for the reasons set forth above, Applicant submits that a *prima facie* case of obviousness has not been satisfied at least because none of the Office Action, the cited references, and the prior art provides a suggestion or motivation for the modifications of the cited references. Consequently, the rejections of the claims under 35 USC §103 should be withdrawn.

Applicants' failure to comment on the reasonable expectation of success and teaching or suggestion elements of a *prima facie* case of obviousness does not constitute an admission that such elements are satisfied, but rather a recognition that such elements are moot based on the remarks herein. Applicants reserve the option to comment on these elements during further prosecution.

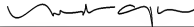
Also, Applicants' failure to argue with particularity against the rejections of the dependent claims does not constitute an acquiescence to those rejections, but rather a recognition that those rejections are moot based on the remarks herein.

CONCLUSION

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 CFR §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 CFR §1.136(a)(3).**

Respectfully submitted,



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